

REMARKS

Reconsideration is respectfully requested.

Claims 1 through 12, 33 through 35, 37 through 39, and 42 through 43 remain in this application. Claims 13 through 32, 36, and 40 through 41 have been cancelled. Claims 44 and 45 have been added.

In part 1 of the Office Action, claims 1 through 6, 33 through 35, 37 through 39 and 42 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Landy et al. (US 4,600,013 A) in view of Miller et al. (US 5,579,774 A) and further in view of Magram (US 5,913,852 A).

In part 2 of the Office Action, claims 7 through 9 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Landy et al. (US 4,600,013 A) in view of Miller et al. (US 5,579,774 A) and further in view of Magram (US 5,913,852 A), as applied to Claims 1 through 6 above, further in view of Knute et al (US 4,903,707 A).

In part 3 of the Office Action, claim 10 was rejected under 35 U.S.C. Section 103(a) as being unpatentable over Landy et al. (US 4,600,013 A) in view of Miller et al. (US 5,579,774 A) and further in view of Magram (US 5,913,852 A), as applied to Claims 1 through 6 above, further in view of Lake (US 3,766,910 A).

In part 4 of the Office Action, claim 11 was rejected under 35 U.S.C. Section 103(a) as being unpatentable over Landy et al. (US 4,600,013 A) in view of Miller et al. (US 5,579,774 A) and further in view of Magram (US 5,913,852 A), as applied to Claims 1-6 above, further in view of Baudino (US 6,110,155 A).

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In part 5 of the Office Action, claim 12 was rejected under 35 U.S.C. Section 103(a) as being unpatentable over Landy et al. (US 4,600,013 A) in view of Miller et al. (US 5,579,774 A) and further in view of Magram (US 5,913,852 A), and further in view of Baudino (US 6,110,155 A), as applied to claim 11 above, further in view of McNeil et al. (US 4,828,546 A).

In part 6 of the Office Action, claim 43 was rejected under 35 U.S.C. Section 103(a) as being unpatentable over Landy et al. (US 4,600,013 A) in view of Miller et al. (US 5,579,774 A) and further in view of Magram (US 5,913,852 A), as applied to Claims 1 through 6 above, further in view Knute et al. (US 4,903,155 A), further in view of Lake (US 3,766,910 A), further in view of Baudino (US 6,110,155 A) and further in view of McNeil et al. (US 4,828,546 A).

It is stated in the most recent, final, Office Action that:

With respect to Applicant's argument on Page 10, 3rd paragraph through Page 11, 2nd paragraph of the response, which is directed to the incorporation of the sealing ridges (27) of Magram to provide an integral mechanism for connecting the tubular portion to a tubular extension for remotely monitoring intercranial pressure into the device of Landy et al.. Magram's sealing ridges provide a generalized teaching of how to attach a conduit to a connector portion of a tubular portion wherein in a fluid-tight connection is desired. The Examiner contends that Magram's sealing ridges (27) would provide a desired fluid-tight seal while simultaneously acting as a frictional connection for Landy et al.'s tube (51) relative to the tubular portion's t-connector (50) end.

It is believed that from the following, it will be come evident that the structure disclosed in the Magram patent, especially when it is taken in the whole context of what both the Magram and Landy patents teach, would not be viewed by one of ordinary skill in the art as a suitable or desirable modification of the Landy device.

In particular, and considering the positions of the Patent Office used to support the rejections, the Office Action states that (emphasis added):

Landy et al.'s heavy plastic tube (51) requires some type of sealing means so as to prevent any leakage at the connection site which could undesirably result in inaccurate measurements, thus incorporation of Magram's sealing ridges on the t-connector end of Landy et al.'s tubular portion would provide a sealing means necessary for the desired fluid-tight and frictional connection.

However, Landy does not show any type of sealing means, and does not disclose any need for sealing means between the low compliance tubing, and so this allegation of the need for a sealing means does not arise from the Landy teaching. So, the need for sealing means is merely supposition by the Patent Office. However, in view of the low compliance nature of the tubing taught by Landy, it is submitted that one of ordinary skill in the art would find it much more suitable to employ a smooth, cylindrical surface on the Landy device (without any structure anticipating the retaining means of claim 1) to be received in the low compliance tubing, and possibly if deemed necessary, the overall outer diameter of the smooth cylindrical surface might be slightly larger than the inner diameter of the tubing.

The argument in the Office Action continues, stating that:

Further, Applicant's assertion that Landy's low compliance, heavy plastic tube would be incapable of incorporation of Magram's sealing ridges is unpersuasive in that one of ordinary skill in the art would have found it to be obvious that a low compliance, heavy plastic tube would still exhibit radial flexibility and as such would be able to benefit from the sealing ridges taught by Magram.

To clarify, the remarks made in the previous Amendment did not take the position that "Landy's low compliance, heavy plastic tube would be *incapable* of incorporation of Magram's sealing ridges", as alleged above. Instead, the applicant put forth reasoning why one of ordinary skill in the art would find such the suggested modification of the Landy device with the Magram ridges *unsuitable*, and thus undesirable, and thus not obvious.

Further, one of ordinary skill in the art, considering the Magram patent, would also note that Magram describes a tube with a flexible and elastically deformable wall. See, e.g., Magram at col. 5, lines 19 through 23, where its states:

The tube typically is of a flexible, elastically deformable material. Inserting the nipple into the lumen causes the tube to stretch around the nipple. The elastic deformation creates a lap joint between the tube and the nipple.

However, the Magram patent does not simply teach the use of ridges in combination with a flexible and elastically deformable tube, but teaches the necessity of using a tubular sleeve formed out of a nonelastic material that encircles the tube and the presses the elastic wall of the tube into the ridges. See, for example, Magram at col. 5, lines 26 through 40:

The novel medical tube coupling additionally includes a generally cylindrically tubular sleeve 26 of a nonelastically deformable material. Non-elastically deformable means that the sleeve material is capable of being deformed to a new shape upon application of sufficient mechanical force, and the sleeve substantially maintains the new shape after the mechanical force is removed. Prior to deformation according to the method of this invention, the sleeve has an internal cavity 25 which is sufficiently large to receive the lap joint. That is, the sleeve fits loosely around the lap joint and is spaced apart by a radial distance from the outside surface of the tube. Upon application of a suitable, radially inwardly directed force to deform the sleeve tightly against the lap joint, the sleeve will clamp the tube to the nipple, thereby enhancing resistance of the tube to disconnect.

Thus, not only does the Magram patent teach the use of the ridges with a tube having a flexible and elastically deformable wall, it also teaches the use of the ridges in combination with a tubular sleeve that is not elastically deformable. Thus, it is submitted that one of ordinary skill in the art, considering the teachings of the Landy and Magram patents, would not find the ridges of Magram to be a suitable modification of the Landy device, as Magram teaches the use of the ridges with a flexible and elastic tube and also in combination with a sleeve to hold the flexible tube onto the ridges to make the connection secure.

The reasoning of the previous Amendment, is reproduced below¹, as the pending Office Action does not dispute the position taken therein that one of ordinary skill in the art would not employ ridges such as taught by Magram with "a low compliance, heavy plastic tube" such as taught by Landy, even if one of ordinary skill in the art was capable of doing so. The issue here is motivation for one of ordinary skill in the art, and certainly not everything that is arguably possible is also desirable. The U.S.P.T.O. Board of Patent Appeals has recognized that not everything that is within the capability of one of ordinary skill in the art is therefore obvious--there must be a motivation provided by the prior art.

The examiner finds the claimed shape would have been obvious urging that (our emphasis) "it is obvious for one skilled in the art to form each hook base of any desired shape *** since *this is within the*

¹ It is alleged in the Office Action that "Magram's sealing ridges provide a generalized teaching of how to attach a conduit to a connector portion of a tubular portion wherein in a fluid-tight connection is desired" and "Landy's heavy plastic tube (51) requires some type of sealing means so as to prevent any leakage at the connection site which could undesirably result in inaccurate measurements". However, merely because the Landy device might need some type of means for connecting the tube 51 to the T-connector 50, does not necessarily mean that a "sealing means" is necessarily required therebetween, as these parts could be integrally formed or molded of a single piece of material so that no need for a "seal" is required. More importantly, even if some type of seal is required between the tube 51 and the T-connector 50, that does not necessarily mean that one of ordinary skill in the art recognizes that any and all means of creating a seal is suitable for use with the "low compliance, relatively heavy plastic tube" that forms the tube 51. As noted previously, one of ordinary skill in the art considering the teaching of Landy understands that the low compliance plastic tube described in Landy is necessary to avoid expansion in the circumference of the wall of the tube 51 to avoid "inaccurate measurements" in the pressure readings made by the pressure transducer 54. In fact, any significant compliance, or flexibility, in the wall of the tube 51 presents a much greater potential possibility for causing inaccurate pressure measurements than the point of connection between the tube 51 and the T-connector 50. As also noted previously, one of ordinary skill in the art would recognize that the ridges 27 of Magram require a significant degree of compliance in the wall of the tube to be able to slide the wall of the tube over the ridges 27. One of ordinary skill in the art would understand that, given the emphasis that Landy places on the low compliance nature of the heavy plastic tube 51 in the Landy apparatus, the ridges of Magram would not be suitable since the Magram ridges inherently require high compliance in the wall of a tube. It is therefore submitted that one of ordinary skill in the art, considering the teaching of Landy, would not look to the ridges of Magram as a suitable structure for connecting the tube 51 of Landy to the T-connector 50 of Landy because one would understand the practical incompatibility of the low compliance, heavy plastic tube of Landy and the ridges of Magram.

capabilities of such a person." Thus, the examiner equates that which is within the capabilities of one skilled in the art with obviousness. Such is not the law. There is nothing in the statutes or the case law which makes "that which is within the capabilities of one skilled in the art" synonymous with obviousness.

Ex parte Gerlach and Woerner, 212 USPQ 471 (PTO Bd. App. 1980) (emphasis in original).

See also, the Manual of Patent Examiner Procedure (MPEP), section 2143.1, where it is stated that (emphasis in original):

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)

Furthermore, there is an additional reason why one of ordinary skill in the art, considering the patents relied upon in the rejection of the Office Action, would not modify the Landy device to include the ridges 27 of Magram. The modification of Landy asserted in the Office Action would require significant effort on the part of the user to slide the "low compliance, relatively heavy plastic tube" taught by Landy over the Magram ridges to create a connection. The magnitude of force that would need to be applied to the low compliance tubing of Landy in order to coax it over the ridges of Magram would not be desirable when the Landy device has already been mounted on the patient's skull, as such force could injure the bore site in the patient's skull, or even possibly dislodge the Landy device from the skull. Thus, in order to avoid this application of force to the bore site when using the allegedly obvious combination set forth in the rejection, the user is left with the undesirable task of mounting the Landy low compliance tubing over the Magram ridges on the Landy device *before* the Landy device can be mounted on the patient's skull, and then mounting the Landy device on the bore in the skull, which requires that the user rotate not only the Landy device, but also the pre-attached low compliance tubing of Landy, as a unit. This operation would clearly be highly awkward, and in light of the

fact that a low compliance tube is not commonly used with any type of ridges because ridges require a significant amount of compliance in the wall of the tube to properly seat on the ridges, it is submitted that one of ordinary skill in the art would not be motivated to modify the Landy device with the Magram ridges as suggested in the Office Action.

The remarks in the pending Office Action go on further to state, with respect to the allegedly obvious modification of the Landy device with the winged handles of Miller, that (emphasis added):

With respect to Applicant's argument on Page 11, 2nd paragraph through Page 12, 1st paragraph of the response, which is directed to the incorporation of the lateral extensions (11) of Miller et al. to provide a gripping means into Landy et al.'s probe. Miller et al.'s lateral extensions provide a surface for applying the necessary torque to thread the bolt into the skull, see Column 8, lines 60-63. The Examiner contends that Miller et al.'s lateral extensions would provide a desired surface for the application of torque by hand, which would obviate the need for an additional tool (i.e. the screw-driver (46)).

According to a well established tenet of patent law, a reference cannot be modified in a manner unsatisfactory to its intended purpose. This tenet of patent law, promulgated by the Federal Circuit, is stated in MPEP 2143.1 as follows:

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)

It is submitted that, the attempt to "obviate the need for an additional tool", in particular the removable wrench 46 of Landy, would change the principle of operation of the Landy device in a manner that would degrade its ability to perform the desired function. As noted in previous Amendments², one of

² It is further alleged in the Office Action that "Miller et al.'s lateral extensions provide a desired surface for the application of torque by hand, which would obviate the need for an additional tool (i.e., the screwdriver (46))" However, Miller does not

Lundy's primary concerns is the size of the device that is left exposed after installation of the device, and Landy's solution is to incorporate a separate and removable wrench that provides a large area from gripping by the user, yet can be removed once the installation of the device has been accomplished. The modification suggested in the Office Action would discard that wrench, and attempt to place "lateral extensions" on the limited portion of the device that remains exposed above the surface of the scalp during installation. It is submitted that this suggested modification is so strange to the teaching of the operation of the device by Landy, that it would have not been obvious to one of ordinary skill in the art that such a modification should be attempted.

The Office Action further states that:

It should first be noted that the placement of the lateral extensions of Miller et al. need not be bodily incorporated into Landy et al.'s device; that is to say that the span of the wings need not be as exaggerated as shown in Miller et al.'s Figure 3 in order to provide sufficient surface for the application of torque. In any event as shown in Figure 4 of Landy et al., the axial length of cylindrical boss (21) and indented segments (22) is longer than bore (38) in which it is received, therefore it would have been obvious to have mounted the lateral extensions on the portions of the cylindrical boss and/or indented segments which are not received in the bore, so as to avoid the need to lengthen the cylindrical boss or increase the overall length of the tubular portion to accommodate the lateral extensions. In addition, with respect to Applicant's assertion that the increased profile of Landy et al.'s probe as a result of the addition of the lateral extensions would be undesirable, the Examiner contends that any slight additional radial extent caused by the incorporation of lateral

suggest to one of ordinary skill in the art that the winged handles are useful for or intended to replace a tool such as the wrench 46 of Landy, and it is again noted that it is Landy (not the applicant) that expresses concern about too much structure being exposed above the scalp of the patient (see Landy col. 1, lines 60 through 63). Landy employs a wrench 46 that is removable after use, and thus can employ radially-extending handles 48 that can be longer than would be practical if the handles were integrated with the shaft 11, therefore making the turning of the shaft 11 easier and permitting the handles to be completely removed from the shaft 11. Shortening the length of the winged handles of Miller, as suggested in the Office Action, permits the user to apply less and less torque to the shaft 11, especially if the winged handles are covered with fluids or blood present at the wound site.

extensions would not necessarily significantly increase the bulk of the device, and would not appreciably increase the probability of inadvertent jarring of the device at the implantation site. Furthermore, any increased jarring which might occur would be mitigated by the increased length of Landy et al.'s probe which acts to securely hold it in place, see Column 3, lines 9-17.

It is noted that in the bore site in the Landy patent, it is a surgical wound site, and thus would be likely be covered in blood and other body fluids that would make the surfaces of the Landy device when introduced into this environment, relatively wet and slippery. It is believed that the contention in the Office Action that the "lateral extensions" of the modified Landy device could be smaller yet still provide sufficient "torque" does not take into consideration that the surgical wound site may have a number of fluids that would make the application of sufficient torque to the reduced surface difficult and vulnerable to slippage of the fingers of the user from the "lateral extensions".

It is further stated in the Office Action that:

Further, Applicant's assertion that shortening the length of the winged handles of Miller et al. would undesirably result in the user being unable to apply sufficient torque is not persuasive in that one skilled in the art would be able to design lateral wings in such a size that would enable the application of manual torque in a sufficient amount without making the device's profile excessively bulky.

Responsive to this assertion, it is noted that the only real evidence of the size of "lateral wings [having] such a size that would enable the application of manual torque in a sufficient amount" is shown in the Landy and Miller patents, and any speculation as to how much smaller the lateral extensions could be is just that--speculation. The Landy and Miller patents provide the best evidence of how large one of ordinary skill in the art would make such lateral extensions. Landy has spoken on the size issue and it is clear from Figure 4 of Landy, in which the handles 48 are shown in indeterminate length to indicate that that are larger than what is shown, and the Miller patent also illustrates relatively large lateral extensions. It is therefore

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submitted that any speculation that the extensions could possibly be made smaller than that shown in Landy or Miller does not reflect what these skilled artisans have taught one of ordinary skill in the art.

It is therefore the applicant's contention that, one of ordinary skill in the art who considers the teaching of Landy without the benefit of the applicant's disclosure, would not be motivated to make the choices and modifications set forth in the Office Action. Although one may be able to come up with various reasons why the modifications might be made, the reasons cannot simply ignore the practical knowledge of those skilled in the art and the concerns expressed by Landy.

It is therefore submitted that the cited references, and especially the allegedly obvious combination of Landy, Miller et al., Magram, Lake, Baudino, and McNeil et al. set forth in the rejection of the Office Action, would not lead one skilled in the art to the applicant's invention as required by claims 1 and 6.

Withdrawal of the §103(a) rejections of claims 1 through 12, 33 through 35, 37 through 39 and 42 through 43 is therefore respectfully requested.

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CONCLUSION

In light of the foregoing amendments and remarks, early reconsideration and allowance of this application are most courteously solicited.

Respectfully submitted,

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